

REMARKS

Claims 1-6, 14-18 and 21-24 are pending in this application. Claims 7-13 and 19-20 are hereby cancelled. Claims 1-4, 14-18 and 21 are currently amended. Claims 23 and 24 are new.

1. Claim 14 was rejected under 35 U.S.C. 102(b) as being anticipated by Sagel et al. (US 2001/0053375).

Regarding Claim 14,

Claim 14 as amended recites:

14. (Currently amended) A kit for the improved whitening of a tooth, which kit comprises:
- (a) a primer-whitener solution comprising hypochlorite and having a pH of greater than about 8.5 up to about 13;
 - (b) a separate peroxide solution; and
 - (c) instructions describing application of said primer-whitener solution to said tooth prior to application of said peroxide solution to said tooth.

The Applicant believes that the amendments to Claim 14 overcome the Examiner's rejection. Specifically, as amended the claims recite separate solutions and instructions relating to timing of solution application. These limitations do not appear to be taught by Sagel. For at least these reasons, the Applicant believes that Claim 14 is allowable.

2. Claims 21-22 were rejected under 35 U.S.C. 102(b) as being anticipated by Ambuter et al. (US 5,997,764).

Regarding Claim 21,

Claim 21 as amended recites:

21 (Currently amended) An improved composition for whitening a tooth surface, which composition comprises:

- (a) a stable pH primer solution itself comprising hypochlorite and having a pH greater than about 8.5 to about 13 which is present in a concentration of between

about 0.1 and 5 weight % of the total composition, said primer solution being configured to synergistically enhance performance of a tooth whitening composition applied to said tooth surface after application of said primer solution; and
(b) a flavoring agent in an amount of between about 0.001 and 5% by weight of the total composition.

The Applicant believes that the amendments to claim 21 overcome the Examiner's rejections. Specifically, as amended the claims recite "said primer solution being configured to synergistically enhance performance of a tooth whitening composition applied to said tooth surface after application of said primer solution." These limitations do not appear to be taught by Ambuter. For example, Ambuter does not teach synergistic enhancement of a tooth whitening composition, or that the tooth whitening composition is applied to said tooth surface after application of said primer solution. For at least these reasons, the Applicant believes that Claim 21 and those claims that depend therefrom are allowable.

Regarding Claim 22, the Applicant believes that Claim 22 is allowable for at least the same reasons as Claim 21, from which it depends.

3. Claims 1-6 and 14-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Howes (US 2002/0098246).

Regarding Claim 1,

Claim 1 as amended recites:

1. (Currently amended) An improved composition for whitening a tooth surface, which composition comprises:
 - (a) a stable pH primer solution itself comprising hypochlorite and having a pH greater than about 8.5 to about 13; and
 - (b) a tooth whitening composition itself comprising peroxide, said tooth whitening composition having been added to said primer solution after said primer solution is applied to said tooth surface.

The Applicant believes that the amendments to Claim 1 overcome the Examiner's rejection. Specifically, as amended Claim 1 recites "said tooth whitening composition having been added to said primer solution after said primer solution is applied to said tooth surface." These limitations do not appear to be taught by Howes.

Further, the Examiner admits that the cited art does not disclose that the hypochlorite solution has a pH greater than about 8.5 to about 13. The Examiner states that it "would have been obvious to one of ordinary skill in the art to have adjusted the pH of the hypochlorite to the alkaline range disclosed motivated by the desire to optimize the reaction between the peroxide and hypochlorite for optimal results." The Applicant traverses this statement.

The Applicant is only aware of one section of the MPEP that supports a claim rejection based on "optimization," namely MPEP §2144.05 directed to the obviousness of ranges. MPEP §2144.05 provides that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." citing *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). However, this MPEP section further states "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation" citing *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Here, the variable that is sought to be optimized is the pH. The Examiner has not shown that the pH is recognized as a result-effective variable, i.e., a variable which achieves a recognized result. Accordingly, the Applicant requests that the Examiner provide evidence that pH was recognized as a result-effective variable for the desired result of tooth whitening at the time the

application was filed, or withdraw the rejection of Claim 1 and the other claims that include similar limitations.

For at least these reasons, the Applicant believes that Claim 1 and those claims that depend therefrom are allowable.

Regarding Claims 2-6, the Applicant believes that Claims 2-6 are allowable for at least the same reasons as Claim 1, from which they depend.

Regarding Claim 14,

Claim 14 as amended recites:

14. (Currently Amended) A kit for the improved whitening of a tooth, which kit comprises:
- (a) a primer-whitener solution comprising hypochlorite and having a pH of greater than about 8.5 up to about 13;
 - (b) a separate peroxide solution; and
 - (c) instructions describing application of said primer-whitener solution to said tooth prior to application of said peroxide solution to said tooth.

The Applicant is unable to identify any teaching within Howes that the solutions of Howes are applied in a sequential manner. Therefore, Howes does not appear to teach “application of said primer-whitener solution to said tooth prior to application of said peroxide solution to said tooth.”

Further, the Applicant believes that Claim 14 as amended is allowable because the cited art does not teach “instructions describing application of said primer-whitener solution to said tooth prior to application of said peroxide solution to said tooth,” as recited in Claim 14. These limitations do not appear to be taught in the prior art. Specifically, the Applicant is unable to find any teaching of “instructions” much less instructions having the characteristics recited in Claim 14.

In addition, as discussed above, it is the position of the Applicant that the Examiner has not shown that the pH is recognized as a result-effective variable and, thus, optimization of pH within the recited range has not properly been shown to be obvious.

For at least these reasons, the Applicant believes that Claim 14, and those claims that depend therefrom are allowable.

Regarding Claim 15, the Applicant believes that Claim 15 is allowable for at least the same reasons as Claim 14, from which it depends

Regarding Claim 16.

Claim 16 recites:

16. (Currently Amended) A kit for improved whitening of a tooth, which kit comprises:
- (a) a first composition of a stable pH primer solution itself comprising hypochlorite and having a pH of greater than about 8.5 up to about 13;
 - (b) means for applying said first pH primer solution to a surface of said tooth;
 - (c) a second tooth whitening composition itself comprising a peroxide;
 - and
 - (d) instructions describing said improved tooth whitening.

The amendments to Claim 16 include primarily the removal of limitations. As such, any new grounds for the rejection of Claim 16 cannot be necessitated by these amendments. The Examiner must, therefore, fully rebut the arguments below in any Advisory Action.

In rejecting Claim 16, the Examiner does not appear to point out a teaching of the limitations “instructions describing said improved tooth whitening process.” For example, the recited instructions describe a tooth whitening process and the cited art does not appear to discuss tooth whitening. Rather, Howes is concerned with “treating tumors, lesions, and cancers,” (Abstract). The Applicant, therefore, requests that the Examiner specifically point out the instructions of Claim 16 in the cited art, or allow Claim 16.

The Applicant points out that the reference to tooth whitening in the element (c) of Claim 16 is more than a mere statement of intended use. Rather, it describes a specific physical characteristic of the “instructions.” The Examiner is reminded that the cited art must teach all of the limitations within the claim for a prima facie case of rejection under 103(a).

In addition, as discussed above, it is the position of the Applicant that the Examiner has not shown that the pH is recognized as a result-effective variable and, thus, optimization of pH within the recited range in Claim 16 has not properly been shown to be obvious.

For at least these reasons, the Applicant believes that Claim 16, and those claims that depend therefrom, are allowable.

Regarding Claims 17 and 18, the Applicant believes that, as amended, the limitations of Claims 17 and 18 are not taught by the cited art. Further, Claims 17 and 18 are allowable for at least the same reasons as Claim 16, from which they depend.

4. Claims 1-4, 6 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over van den Bosh (US 6,017,515).

It is the Applicant’s position that the rejections of Claims 1-4, 6 and 14-17 under 103(a) over van den Bosh have been overcome for the same reasons as discussed above with regard to the rejections based on Howes, Ambuter and Sagel. Specifically, the van den Bosch does not appear to teach separate solutions and instructions relating to timing of solution application as recited in Claim 1. Further, van den Bosch does not appear to teach “instructions describing application of said primer-whitener solution to said tooth prior to application of said peroxide solution to said tooth,” as recited in Claim 14. Further, van den Bosch does not appear to teach “instructions describing said tooth whitening,” as recited in Claim 16.

In addition, as discussed above, it is the position of the Applicant that the Examiner has not shown that the pH is recognized as a result-effective variable and, thus, optimization of pH within the recited range has not properly been shown to be obvious.

5. Claims 1-6, 14-17 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jung (US 2006/0060819).

It is the Applicant's position that the rejections of Claims 1-6, 14-17 and 21-22 under 103(a) over Jung have been overcome for the same reasons as discussed above with regard to the rejections based on Howes, Ambuter and Sagel. Specifically, the Jung does not appear to teach separate solutions and instructions relating to timing of solution application as recited in Claim 1. Further, Jung does not appear to teach "instructions describing application of said primer-whitener solution to said tooth prior to application of said peroxide solution to said tooth," as recited in Claim 14. Further, Jung does not appear to teach "instructions describing said improved tooth whitening process," as recited in Claim 16. Finally, Jung does not appear to teach "said primer solution being configured to synergistically enhance performance of a tooth whitening composition applied to said tooth surface after application of said primer solution," as recited in Claim 22.

In addition, as discussed above, it is the position of the Applicant that the Examiner has not shown that the pH is recognized as a result-effective variable and, thus, optimization of pH within the recited range has not properly been shown to be obvious.

SUMMARY

Applicant argues that with these amendments, the now pending claims are of a form and scope for allowance.

Respectfully submitted,

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